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Section 2.1

510(k) Summary of Safety and Effectiveness Information in This Submission

The following is a summary of the safety and effectiveness statements and data contained in this pre market notification for the Spegas MicroCap/NPB-75 capnograph/pulse oximeter.

PRODUCT NAME

Proprietary: MicroCap/NPB-75

Common: Combination Oximeter/Carbon Dioxide Gas Analyzer

ESTABLISHMENT REGISTRATION NUMBER

Establishment Registration Number: 8044004

ESTABLISHMENT ADDRESS:

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DEVICE LISTING FDA FORM 2892: A 733250

DEVICE DESCRIPTION

The Spegas MicroCap/NPB-75 and the comparison device Gemini+ (K950387) are integrated instruments that measure end tidal CO₂ (EtCO₂) and saturated arterial oxygen (SpO₂). As a derivative of the EtCO₂ measurement the devices measure and display the breath rate (BR) and as a derivative of the saturated arterial oxygen measurement the devices measure and display the pulse rate (PR). The capnograph section of both devices function as a carbon dioxide gas analyzer that measures in mmHg, Vol %, or kPa the concentration of CO₂ in a gas mixture to aid in determining the patient's ventilatory status. The pulse oximeter module in both devices measures the oxygenated hemoglobin (HbO₂) and displays the results as a percent of oxygen and as a plethysmographic waveform. The Spegas MicroCap/NPB-75 pulse oximeter module is essentially identical to the Spegas Gemini+ (K950387) pulse oximeter module. The Gemini+ uses the Nellcor M-203 SpO₂ module and the MicroCap/NPB-75 utilizes the Nellcor MP-204 module. The MP-204 SpO₂ module is very similar, essentially equivalent, to the MP-203 module. Spegas integrates the Nellcor MP-204, without alteration, into the MicroCap/NPB-75 and Gemini (MP203).

SUBSTANTIAL EQUIVALENCE INFORMATION

The new device, the MicroCap/NPB-75, is a two parameter monitor incorporating the functions of currently marketed two parameter monitors. It is substantially equivalent, in terms of indications for use and technological characteristics to the two parameter Spegas Gemini+ capnograph/ pulse oximeter (K950387).